JAN 2 3 2006

510(k) SUMMARY K060050

Biolitec MegaBeam® SideFiber® Fiber Optic Delivery System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Biolitec, Inc
515 Shaker Road
EastLongmeadow, MA 01028

Phone: (413) 525 0600
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Contact Person: Carol J. Morello, VMD

Date Prepared: January 6, 2006

Name of Device

MegaBeam SideFiber Fiber Optic Delivery System (Model SF-2100-H)

Common or Usual Name

Ho:YAG Fiber Optic Delivery System

Classification Name

Accessory to Laser Surgical Instruments

Predicate Devices

Biolitec Inc MegaBeam Lateral Fire Fiber Optic Delivery System
Lumenis DuoTome Side Firing Fiber
Trimedyne VAPORMAX side firing fiber

Intended Use / Indications for Use

The Model SF-2100-H MegaBeam SideFiber Fiber Optic Delivery System is intended for use as a fiber optic delivery system in conjunction with any Ho:YAG (holmium) surgical laser with SMA 905 compatible connector. The MegaBeam SideFiber Fiber Optic Delivery System is indicated for hemostasis, ablation and vaporization of soft or fibrous tissue in any surgical discipline with a compatible laser marketed for the desired application. The system can be used with or without a standard viewing scope. It can be inserted through the working channel of a cystoscope, urethroscope, or any other viewing scope.

K060050

Technological Characteristics

The SF-2100-H MegaBeam SideFiber Fiber Optic Delivery System consists of quartz fiber core and a coaxially mounted protective sheath with a metal tip at the distal end.

Performance Data

Bench test data was provided in support of the 510(k) notice.

Substantial Equivalence

The SF-2100-H MegaBeam SideFiber Fiber Optic Delivery System is as safe and effective as the Biolitec MegaBeam Lateral Fiber (SideFiber) Fiber Optic Delivery System. The MegaBeam Lateral Fiber Optic Delivery System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the MegaBeam Fiber Optic Delivery System and its predicate devices raise no new issues of safety or effectiveness. Thus, the MegaBeam Fiber Optic Delivery System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2006

Biolitec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan and Hartson, L.L.P.
555 13th Street, NW
Washington, District of Columbia 20004-1109

Re: K060050
Trade/Device Name: MegaBeam SideFiber Fiber Optic Delivery System (Model SF-2100-H)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 6, 2006
Received: January 6, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

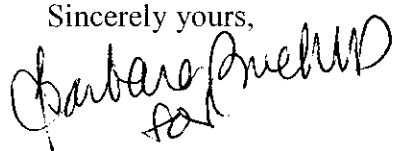
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060050

Device Name:

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucholz for MTM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060050